UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

"Track 3 Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

DEFENDANTS' JOINT MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(A) AND MEMORANDUM OF LAW IN SUPPORT

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INTRODUCTION

Plaintiffs have failed to prove that any Defendant committed acts that could support a jury finding of nuisance liability under the legal framework set out in this Court's ruling on Defendants' motion to dismiss. At most, Plaintiffs have questioned whether Defendants failed to comply with what Plaintiffs' experts would consider pharmacy "best practices." But even if Plaintiffs' experts are right about such "best practices" (and they are not), a failure to comply with a standard of care, without more, can only establish an actor's *negligence*. Under Ohio law, though, negligence can establish a claim only for *qualified nuisance*. An *absolute nuisance*, by contrast, requires proof of either unlawful conduct or intentional and culpable conduct. Plaintiffs press only absolute nuisance, and they have not presented legally sufficient evidence of either unlawful or intentional conduct. Nor have they introduced evidence from which a reasonable jury could conclude that any Defendant was a substantial factor in creating an ongoing nuisance. Judgment as a matter of law is therefore necessary.

Plaintiffs' public nuisance claim should not have made it this far. Their case is legally deficient for many reasons that do not depend on the evidence offered at trial. Among other things, the Controlled Substances Act ("CSA") duties Plaintiffs allege that Defendants breached do not actually exist and are precluded by Ohio nuisance law. And the proper party to enforce any CSA requirements is the U.S. Drug Enforcement Administration ("DEA"), not two political subdivisions whose built-for-litigation theories will only disrupt the doctor-patient relationship to the detriment of patient health. Recognizing that the Court has rejected these arguments, Defendants restate them in the second half of their brief for preservation purposes.

LEGAL STANDARD

"Under Rule 50, a court should render judgment as a matter of law when 'a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury

to find for that party on that issue.'" *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 149 (2000) (quoting Fed. R. Civ. P. 50(a)). "[T]he standard for granting . . . judgment as a matter of law . . . is the same" as for granting summary judgment. *Id.* at 150 (quotation marks omitted). "[A] Rule 50(a) motion should not be reviewed narrowly but rather in light of the purpose of the rules to secure a just, speedy, and inexpensive determination of the case." *Kusens v. Pascal Co.*, 448 F.3d 349, 361 (6th Cir. 2006).

ARGUMENT

I. EVEN UNDER PLAINTIFFS' AND THE COURT'S VIEW OF THE LAW, DEFENDANTS CANNOT BE HELD LIABLE FOR AN ABSOLUTE PUBLIC NUISANCE.

In Ohio, a public nuisance can be either absolute or qualified: A qualified nuisance depends on proof of negligence, while an absolute nuisance requires proof of either unlawful conduct or intentional and culpable conduct. *See, e.g.*, *Barnett v. Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001); Black's Law Dictionary (11th ed. 2019) (defining "culpable" as "guilty," "blameworthy," or "involving the breach of a duty"). Plaintiffs have eschewed any qualified nuisance claim, instead raising a claim under the absolute nuisance doctrine only. Because there is "no legally sufficient evidentiary basis" for a reasonable jury to find that Defendants acted either (1) unlawfully or (2) intentionally and culpably, the Court should direct judgment for Defendants, even under Plaintiffs' view of the law and this Court's earlier decisions. *Reeves*, 530 U.S. at 149 (quoting Fed. R. Civ. P. 50(a)).

A. The Court Should Grant Judgment as a Matter of Law as to Defendants' Distribution Conduct.

Plaintiffs have produced no legally sufficient evidence that any Defendant engaged in unlawful distribution conduct or that such conduct caused their alleged injuries. Thus, the Court should grant Defendants judgment as a matter of law.

1. Plaintiffs have not adduced legally sufficient evidence of unlawful distribution conduct.

Plaintiffs have not adduced evidence sufficient to establish that any distribution-related conduct by any Defendant violated the CSA such that Defendants could be held liable under the "unlawful" prong of absolute public nuisance. To begin, Plaintiffs have not adduced evidence from which a reasonable jury could conclude that any Defendant violated the CSA's regulation of drug distribution. To implement the CSA, Congress empowered DEA to authorize an entity to distribute or dispense controlled substances, so long as DEA determines that it is in the "public interest." 21 U.S.C. §§ 822(b), 823(b). In making that assessment, DEA must consider, among other things, the distributor's maintenance of "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," *id.* §§ 823(b)(1), (e)(1), including by "design[ing] and operat[ing] a system" to monitor suspicious orders, 21 C.F.R. § 1301.74(b).

This Court has recognized that the CSA, analogous Ohio laws, and those laws' implementing regulations "do not require strict compliance." Dkt. 3913 at 5 (Order Denying Giant Eagle's Motion for Summary Judgment). Instead, DEA may issue a registration based on only substantial compliance. *See* 21 C.F.R. § 1301.71(b); OAC-4729-9-05. At trial, Plaintiffs' expert and former DEA official Joe Rannazzisi agreed that the "DEA leaves the development and operation of a [Suspicious Order Monitoring System] to the registrant[s][,]" and that there was no "official checklist" for self-distributors because "they know their customer base, they know their employees, and they know their capabilities at their distribution facilities." Dkt. 4023 at 131 (Oct. 13 trial tr., vol. 7).[1]

[1] All trial citations are to ECF daily transcripts.

Plaintiffs have not presented legally sufficient evidence showing that any Defendant has failed to maintain adequate controls. It is undisputed that DEA registered each Defendant to distribute controlled substances, for each year at issue, based on DEA's determination that the registration was in the public interest, including based on DEA's assessment of their controls. And although they retained an expert specifically on distribution systems, James Rafalski, Plaintiffs elected not to call him to testify at trial.

Instead, former DEA agent Joe Rannazzisi testified about the 2006 and 2007 "Dear Registrant" letters he drafted. But that non-binding, sub-regulatory guidance only reminded distributors "to be vigilant" about regulations that had existed "[s]ince around 1970" because DEA was seeing "opioid prescriptions on the rise." Dkt. 4017 at 247, 250, 252 (Oct. 12 trial tr., vol. 6); Admitted Exs. P-00035, P-00036. They simply "remind[ed] [distributors] what their responsibilities [we]re," and created no new responsibilities. Dkt. 4017 at 249 (Oct. 12 trial tr., vol. 6); P-00035 ("The purpose of this letter is to reiterate the responsibilities of controlled substance distributors"); P-00036 (same). The letters did not catalog any particular deficiencies regarding any existing monitoring systems, much less establish regulatory requirements. *See* P-00035; P-00036.

Even if they did establish a new requirement (and they did not), the letters were sub-regulatory and non-binding: Letters or other so-called "guidance" documents that express an agency official's view of the law "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995). Even *agency adjudications* (which "Dear Registrant" letters are not) result in an order that is binding only on the entity who is a party to the adjudication and do not impose controlling legal requirements beyond that entity. *See NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 (1969)

(plurality op.). Plaintiffs' attempt to rest distribution-based liability on the most slender of reeds is thus legally insufficient.

The jury heard almost no testimony about what Defendants' suspicious order monitoring systems even involved, let alone what alleged flaws they had or how those flaws violated the CSA. There is thus no way for them to even begin to appraise the legality of Defendants' monitoring systems.

2. Plaintiffs have failed to establish that Defendants' distribution conduct caused a public nuisance in their Counties.

Furthermore, Plaintiffs have introduced no evidence that can establish that distribution-related conduct caused a present-day nuisance. "[T]he tort of public nuisance only reaches so far[,]" *Cleveland v. JP Morgan Chase Bank, N.A.*, No. 98656, 2013 WL 1183332, at *3 (Ohio Ct. App. Mar. 21, 2013), and "not every failure to comply with [a regulation] amounts to a public nuisance[,]" *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 479 (6th Cir. 2017). The plaintiff must show, in addition, that the violation substantially interfered with public health and safety, *id.*, and that the defendant was a "substantial factor" in causing the alleged harm, Restatement (Second) of Torts § 834 cmt. d (1979).

An actor's conduct is not a substantial factor if the harm would have been sustained even without the misconduct. Restatement (Second) of Torts § 432 (1965). Three considerations determine whether a cause is a substantial factor: "(a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it; (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible; [and] (c) lapse of time." *Id.* § 433.

Even more, "to support a verdict and judgment" for public nuisance, a plaintiff must "show[] by the evidence that the injury incurred was the *proximate result* of the maintenance of such nuisance." *Gaines v. Vill. of Wyo.*, 72 N.E.2d 369, 373 (Ohio 1947) (emphasis added). Plaintiffs cannot meet these standards, and particularly not with respect to distribution conduct.

Plaintiffs' data expert, Craig McCann, introduced only *dispensing* data into the record, not *distribution* data.[2] As a result, the record is simply silent on how many opioids Defendants distributed to themselves, and so a reasonable juror cannot determine whether and how any Defendant's self-distribution (as opposed to distribution to Defendants by, say, one of the major wholesale distributors) contributed to the "massive increases in the supply of prescription opioids" into Lake and Trumbull Counties, as required by this Court's rulings. Dkt. 2561 at 8 (Order Denying Distributors' Motions for Summary Judgment on Causation). Nor have Plaintiffs identified a single actual "suspicious" order shipped to Track 3 counties by any Defendant, let alone in violation of the CSA.

These omissions are fatal: Plaintiffs must prove their claims against each Defendant based on each Defendant's alleged wrongdoing, and must prove that each Defendant's contribution to their injuries was "substantial." *See Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990). Plaintiffs cannot do so on this record.

Moreover, Plaintiffs' distribution claims are causally dependent on their dispensing claims. Defendants distributed only to their own pharmacies. And Plaintiffs have never argued, much less adduced any evidence, that prescription medications left Defendants' pharmacies by any means other than filling prescriptions. So if Defendants somehow "oversupplied" opioid medications in

[2] Although Plaintiffs marked the ARCOS data set for identification, no witness presented or interpreted the data for the jury and thus it is of no consequence. In fact, there is no indication that any juror can even access this data.

Lake and Trumbull Counties (they did not), on Plaintiffs' own theory of the case, it was by *dispensing*, not distribution. In other words, absent a dispensing violation, Plaintiffs have no evidence of any distribution that caused any harm. The Court should grant judgment as a matter of law for lack of causation as to Plaintiffs' distribution-based claims.

B. The Court Should Grant Judgment as a Matter of Law as to Defendants' Dispensing Conduct.

Likewise, Plaintiffs have produced no legally sufficient evidence that any Defendant engaged in unlawful dispensing conduct or that such conduct caused their alleged injuries, and thus judgment as a matter of law is warranted.

1. Plaintiffs have not adduced legally sufficient evidence of unlawful dispensing conduct.

Plaintiffs have not adduced legally sufficient evidence of unlawful dispensing conduct by any Defendant. Any dispensing duties imposed on Defendants must derive from the CSA's text or its regulations. No one disputes that Defendants complied with the physical security, recordkeeping, and other requirements expressly provided by those sources of law. That resolves any question of whether Defendants' dispensing practices were unlawful. *See infra* Section II.C.1.

At the motion-to-dismiss stage, however, this Court held that Defendants are subject to additional dispensing-related duties at the corporate level, including "an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly." *See* Dkt. 3403 at 25; Dkt. 3499 at 15. Defendants continue to disagree with that ruling. *See, e.g.*, Dkt. 3439 (Pharmacy Defendants' Motion for Reconsideration or Certification of Order Denying Motion to Dismiss). Even assuming the law actually does impose those additional requirements, however, Plaintiffs have not introduced evidence that any Defendant violated them.

As the Court has recognized, Plaintiffs must clear a steep hurdle to prove a breach of a dispensing-related duty: Plaintiffs must show that Defendants acted with "deliberate ignorance"

or "willful blindness," not merely recklessly or negligently. Dkt. 3499 at 7. That is a demanding standard to meet. To be "willfully blind," a defendant must have taken "deliberate actions to avoid confirming a high probability of wrongdoing[.]" *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011) (citing G. Williams, Criminal Law § 57, at 159 (2d ed. 1961)); *see also* Black's Law Dictionary ("Deliberate avoidance of knowledge."). The defendant must have essentially "actually known the critical facts"—by "subjectively believ[ing] that there is a high probability that a fact exists" and by taking "deliberate actions to avoid learning of that fact." *Glob.-Tech Appliances*, 563 U.S. at 769. To clear this hurdle, Plaintiffs were required to present evidence that each Defendant (1) subjectively believed its pharmacists were violating the CSA and (2) intentionally took actions to avoid learning about it. *See id.*

Plaintiffs attempt to demonstrate willful blindness in two ways, but neither finds any basis in the CSA, and neither is remotely sufficient to show that any Defendant acted with willful blindness. *First*, Plaintiffs fault Defendants for not adequately sharing prescription data from one pharmacist to another. *See, e.g.*, Dkt. 4005 at 301 (Oct. 7 trial tr., vol. 4) (stating Catizone's Opinion 13 as "[e]ach defendant failed to provide its pharmacists with data, information and the tools necessary to assist the pharmacists in fulfilling their corresponding responsibility duties, including but not limited to utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion, as well to recognize and resolve red flags"). *Second*, Plaintiffs seek to hold Defendants responsible for not informing their pharmacists of certain "red flags" Plaintiffs' expert has specified and for not requiring their pharmacists to document the resolution of such red flags. *See, e.g.*, *id.* at 259 (stating Catizone's Opinion 10 as "[e]ach defendants' local stores filled thousands of prescriptions presenting red flags without evidence of resolving those red flags").

Data-Sharing. The Court already has ruled that the CSA does not require any data to be shared among a chain's individual pharmacists, explaining that "there is no absolute requirement . . . that a pharmacy must conduct a computerized [] analysis of each prescription before filling it." Dkt. 3499 at 7. And, in any event, Defendants *did* share data about prescriptions across all pharmacies, through Ohio's prescription drug monitoring program, OARRS (Ohio Automated Rx Reporting System), which tracks the dispensing of controlled prescription drugs statewide, and other Defendant-specific proprietary programs. Dkt. 4008 at 67–68 (Oct. 8 trial tr., vol. 5). The mere fact that their systems arguably could have been more advanced in no way suggests that any Defendant took "deliberate actions to avoid confirming a high probability of wrongdoing," as required to establish willful blindness. *Glob.-Tech Appliances*, 563 U.S. at 769. Plaintiffs' second-guessing about "best practices" is at most a negligence theory; it certainly does not show knowledge.

Red Flags and Documentation. Plaintiffs assert that Defendants were willfully blind because they did not instruct their pharmacists about the 16 "red flags" Plaintiffs' expert identified and because they did not require their pharmacists to document the resolution of such red flags.

Neither the CSA nor its Ohio analog comes close to supporting this deeply flawed approach. The phrase "red flags" itself does not appear anywhere in the CSA, any DEA regulation, or any analogous Ohio law or regulation. More importantly, those sources of law do not contain any list of specific indicators, much less the 16 specific "red flags" listed by Plaintiffs' expert, or suggest that any such list should be rigidly followed. Nor do they contain any mandate to document the resolution of those indicators. So, the mere fact that an individual pharmacist might not have fully documented how he or she resolved one of these "red flags" later enumerated by Plaintiffs' expert says nothing about the pharmacist's mental state at the time of dispensing.

Across the board, Plaintiffs' dispensing theory lacks a legal foundation and therefore cannot be the basis of a jury verdict.

Plaintiff's expert, Catizone, testified that these responsibilities emanated from the "customary scope of pharmacy practice"—a dubious proposition in and of itself. Dkt. 4005 at 293 (Oct. 7 trial tr., vol. 4). At trial, he could not name even a single pharmacy anywhere in the world that actually follows the method he proposed, explaining that he never bothered to study the matter. *See* Dkt. 4008 at 149–50 (Oct. 8 trial tr., vol. 5). Simply put, a practice that not one pharmacy follows cannot be considered "customary." *Custom*, Black's Law Dictionary (a practice defined by "common adoption and long, unvarying habit"). Customs also change over time, and it has been over 20 years since Catizone was last a pharmacist. *See* Dkt. 4017 at 304–05 (Catizone testimony, Oct. 12 trial tr., vol. 6).

Even putting that objection aside does not help Plaintiffs escape judgment as a matter of law, though: Neither the CSA nor its implementing regulations incorporate pharmacy "custom," and thus Plaintiffs cannot ground their novel theory in any legal requirement. It is possible that Plaintiffs will argue any supposed "red flag" prescription dispensed without documentation is not filled "in the usual course of [the pharmacist's] professional practice." 21 C.F.R. § 1306.06. But it is far too late in this litigation to raise that argument for the first time and, in any event, it is plainly wrong. A pharmacist does not violate § 1306.06 or any other law or regulation simply by filling one or more prescriptions hitting on Catizone's "red flags." The Supreme Court has explained that acting outside "the usual course" of one's profession means abandoning all professional norms to the point of no longer acting in a professional capacity. *United States v. Moore*, 423 U.S. 122, 143 (1975) (physician "did not regulate the dosage at all, prescribing as

much and as frequently as the patient demanded").[3] A putative failure to follow Plaintiffs' proposed protocol is a far cry from abandoning all professional norms, particularly when Plaintiffs failed to establish that even *a single pharmacy*—not to mention the industry as a whole—adheres to their fabricated model. *See* Dkt. 4008 at 149 (Oct. 8 trial tr., vol. 5).

The regulation thus does not purport to mandate whatever courts, Plaintiffs' lawyers, or hired experts might believe are best practices for pharmacists. Nor could it. For one thing, that sweeping interpretation would present fatal vagueness problems. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). For another, it would swallow and render superfluous the more specific regulation governing dispensing, § 1306.04(a), which carefully forbids only ***knowingly*** filling illegitimate prescriptions. If § 1306.06 were construed to codify professional standards for pharmacists and require them to follow certain procedural steps before filling prescriptions, § 1306.04(a) would do nothing. Indeed, this Court has made clear that Defendants *could not have violated the CSA* if they did not act with the requisite scienter: that they were "deliberately ignorant or willfully blind." Dkt. 3499 at 7. In any event, Plaintiffs' interpretation would offend federalism principles by turning the paradigmatic state power over professional standards into a matter of federal law. *See Jones v. United States*, 529 U.S. 848, 858 (2000) (courts disfavor interpretations that upset federal-state balance by extending "federal enforcement" over "traditionally local" matters).

[3] Specifically, in *Moore*, the Supreme Court affirmed jury instructions that allowed liability for a physician for prescribing that was "other than in good faith" and stated that the defendant could not be found guilty if he "made 'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice." 423 U.S. at 139, 142 n.20 (citation omitted); *see also United States v. Volkman*, 797 F.3d 377, 387 (6th Cir. 2015) (affirming instructions that "good faith" in this context "means good intentions and an honest exercise of professional judgment as to a patient's medical needs. It means that the defendant acted in accordance with what he reasonably believed to be proper medical practice").

Recognizing this infirmity, Plaintiffs might attempt to focus on *documentation* as opposed to the red flags themselves. Although the ground for any such argument was not well-articulated at trial, Plaintiffs allude to several additional sources of law besides 21 C.F.R. § 1306.06 for their claim that Defendants' pharmacists had to *document* the resolution of red flags, but none imposes such a duty:

First, Plaintiffs cite 21 C.F.R. § 1306.04(a), which forbids "knowingly fill[ing]" an invalid prescription. But the absence of documentation of the resolution of red flags is not evidence of knowledge (or willful blindness). There are several other rational explanations for why such things are not always documented exactly the way that Plaintiffs suggest. Imagine, for example, that a customer presents a prescription written by a doctor far from the pharmacy. While this might raise questions, it also might not: The pharmacist might, for instance, know from past encounters that the customer works near the pharmacy but lives near the doctor, so the prescription is legitimate. Dkt. 4008 at 165–66 (Oct. 8 trial tr., vol. 5). That pharmacist satisfies her corresponding responsibility—by not "knowingly fill[ing]" an invalid prescription—even if she conducts no investigation and never records why she believes the doctor wrote the prescription in the usual course of treatment. 21 C.F.R. § 1306.04(a). Plaintiffs have offered no evidence that the reason Defendants' pharmacists did not systematically document the resolution of their concerns was because they were hiding improper prescriptions—or had a desire to remain ignorant about whether a prescription was improper. Indeed, Plaintiffs have failed to establish that any individual pharmacist actually harbored suspicions at the time he or she filled any particular prescription. Even Plaintiffs do not contend that failing to document the investigation of every prescription written by a doctor outside of a 25-mile radius, for example, constitutes willful blindness, and no

evidence suggests any such contention otherwise. *See, e.g.*, Dkt. 4008 at 152–53 (Oct. 8, trial tr., vol. 5).

The same holds true for Ohio law. Although pharmacists must "us[e] [their] professional judgment" to "take appropriate steps to avoid" problems including abuse, misuse, drug interactions, and allergies, there is no rigid list of "flags" that triggers a duty not to fill, nor is there any associated documentation requirement. Ohio Admin. Code § 4729-5-20(A). Most importantly, unwittingly failing to follow the "best practices" opinions crafted after the fact by Plaintiffs' expert witness would at most support a claim of negligence. That is no help to Plaintiffs, however, because negligence is cognizable only in a qualified nuisance claim—and Plaintiffs do not make any such claim here. *Carr*, 2001 WL 1078980, at *10–11.

Second, 21 U.S.C. § 827(a) does not provide the support for a "red flag" documentation requirement. That provision requires every registrant to "maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him[.]" No one disputes that Defendants did exactly that. Instead, the dispute here concerns whether the CSA requires the documentation of the *resolution of suspicions*, not documentation of drugs dispensed. The regulation requires no such thing.

Third, Plaintiffs fall back on a pair of agency adjudications: *Paul H. Volkman*; *Denial of Application*, 73 Fed. Reg. 30,630-02 (May 28, 2008), and *Hills Pharmacy, LLC*; *Decision and Order*, 81 Fed. Reg. 49,816 (July 28, 2016). In *Volkman*, DEA suspended the registration of a physician who kept no record of the drugs he prescribed for an entire year and generally exhibited "wholly deficient recordkeeping." 73 Fed. Reg. at 30,643. Likewise, the pharmacy in *Hills Pharmacy*, "failed to complete a biennial inventory," "note the date and quantity it received of schedule II drugs," or keep its records "readily available." 81 Fed. Reg. at 49,816. Nobody

contends that any Defendant here failed to keep complete and accurate logs of all medications they dispensed. Therefore, these agency adjudications have nothing to do with this lawsuit.

In sum, Plaintiffs' novel "red flags" provide no basis for believing any pharmacist actually harbored any suspicions at the time of dispensing a particular prescription, and their documentation rules are at most Plaintiffs' expert's opinion as to what constitutes "best practices"; they find no basis in the CSA or its regulations. The fact that Defendants did not adopt Plaintiffs' model is not evidence of willful blindness. Thus, under this Court's governing rulings, judgment must be granted for Defendants on their dispensing conduct.

2. Defendants' dispensing conduct did not proximately cause Plaintiffs' alleged injuries.

Plaintiffs have presented no legally sufficient evidence that Defendants' dispensing conduct proximately caused Plaintiffs' alleged harm.

No evidence of any particular wrongful orders or prescriptions. Plaintiffs say that Defendants' failure to identify suspicious prescriptions caused their harm. But Plaintiffs have introduced no evidence that any particular prescription was in fact illegitimate. Moreover, Plaintiffs have presented no evidence of what would have happened if Defendants had investigated and attempted to dispel the suspicion for any particular order or prescription flagged by Plaintiffs' experts. Without this evidence, Plaintiffs cannot "establish[] proximate cause": They cannot show that Defendants "would have detected the presence" of illegitimate prescriptions, even assuming some existed. *Burnworth v. Harper*, 672 N.E.2d 241, 245 (Ohio Ct. App. 1996).

No evidence of any diverted or misused Defendant prescriptions. Even if they had evidence of suspicious prescriptions that (1) were in fact illegitimate and (2) Defendants could have detected and prevented them from being filled, Plaintiffs have introduced no evidence whatsoever that any of those prescriptions were in fact diverted or misused in any way. Diversion or misuse is the key

link in Plaintiffs' alleged causal chain. Without evidence that prescription opioid medications from *Defendants'* pharmacies actually were diverted or misused, Plaintiffs cannot establish causation. And Plaintiffs must establish proximate cause separately for each defendant; aggregate proof is not enough. *See Sutowski*, 696 N.E.2d at 190; *Pang*, 559 N.E.2d at 1324. To show harm, Plaintiffs had to show actual diversion or misuse, and they have not shown that a single pill left any of Defendants' pharmacies improperly—that is, with knowledge that it was improper.

No causal chain regardless. Even if Plaintiffs had introduced evidence of illegitimate prescriptions filled at each of Defendants' pharmacies that were later diverted, which they did not, they still cannot show that Defendants proximately caused their alleged injuries.

First, Defendants' relationship to Plaintiffs' alleged harm is too far remote to establish causation. Defendants' Lake County and Trumbull County pharmacies played only a tiny—and far-down-the-chain—part in the supply chain. At most, then, they could have had only an *indirect* and *remote* connection to Plaintiffs' alleged injuries. When a public-nuisance defendant plays such a role, it cannot be held liable. *See City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 503–04 (6th Cir. 2010) (collecting cases deciding remoteness as a matter of law); *see also Cincinnati v. Beretta USA Corp.*, 768 N.E.2d 1136, 1147–48 (Ohio 2002) (adopting directness requirement from *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992)).

A nuisance suit fails this directness requirement when "there is another set of independent actors between the alleged misconduct and the alleged injury." *Ameriquest*, 615 F.3d at 505. For a chance at establishing liability, then, Plaintiffs must point to evidence establishing a "direct relation between the injury asserted and the injurious conduct alleged." *Id.* at 502 (citations omitted). "Notably, this requirement is distinct from foreseeability and applies even if the [d]efendants intentionally caused the alleged course of events." *Id.*

There are numerous "intervening factors necessary for the harm suffered by the [Counties] to materialize," making Defendants' role too far remote for liability. *Chase*, 2013 WL 1183332, at *3. To name just a few of the factors necessary to have brought about Plaintiffs' harm, *according to Plaintiffs themselves*: the Manufacturer Defendants (Purdue, Cephalon, Janssen, Endo, and Mallinckrodt), in concert with the Supply Chain Defendants (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen), allegedly changed the standard of care for pain treatment by misrepresenting the dangers and effectiveness of opioids, thereby leading doctors, with encouragement of the government, to prescribe opioids in unreasonable numbers. *See In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2018 WL 6628898, at *5 (N.D. Ohio Dec. 19, 2018). But none of this is related to any Defendant's dispensing. According to Plaintiffs, individual pharmacists unwittingly filled prescriptions that should not have been filled, and individuals receiving the prescriptions abused or diverted them to the illegal market. This Court has held that the Manufacturers (and to a lesser extent the Distributors) may be close enough to a county's claimed injury to survive the directness requirement on the pleadings, because their marketing directly caused "excess opioids" in the counties. *Id.* ("Under this potential chain of causation, the relationship between Plaintiffs' injury and Defendants' alleged conduct . . . is not too remote to support a finding of proximate cause."). Dispensing by CVS, Walgreens, and Walmart, on the other hand, is "completely distinct from th[at] asserted misconduct[.]" *Ameriquest*, 615 F.3d at 504. It is several steps further removed from Plaintiffs' claimed injuries, and even one step removed defeats directness. *See, e.g.*, Dkt. 3253 at 18 (Opinion and Order granting in part and denying in part Defendants' Motions to Dismiss in *West Boca*, suggesting no remoteness for an injury "at least one step further removed from the [allegedly] injurious conduct. . . .").

The trial testimony of Plaintiffs' expert, Dr. Katherine Keyes, merely underscored the remote relationship between Defendants' conduct and Plaintiffs' alleged injury here. She noted that she was tasked with measuring "a complex system" with many "individual vulnerabilities" and "other community level factors." Dkt. 4065 at 89 (Oct. 22, trial tr., vol. 14). She agreed that major wholesale distributors and drug manufacturers causally contributed to the burden. *Id.* at 96–97. She also stated that even government entities, including the U.S. Food and Drug Administration, DEA, and state medical boards, were "points in [the] access pathway" and played a causal role for their lack of adequate regulation. *Id*. at 95. Keyes even admitted that if the opioid manufacturers had "acted more responsibly" and the FDA had "done its job," there would not have been an opioid crisis. Dkt. 4090 at 125 (Oct. 26 trial tr., vol. 16). Plaintiffs' expert Dr. Caleb Alexander, for his part, agreed that he had testified that "the origins of the epidemic are multiple [] including unsubstantiated claims about the safety and effectiveness of opioids, multifaceted campaigns by pharmaceutical companies, and the failure of the FDA and DEA," and that Manufacturers, the FDA, and DEA—not pharmacies—were the "major causes of the opioid epidemic." Dkt. 4064 at 203, 230 (Oct. 21 trial tr., vol. 13). Thus, Defendants' dispensing cannot be the proximate cause of Plaintiffs' asserted injuries. *See, e.g.*, *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006).

The harm supposedly caused by each Defendant's dispensing, as opposed to any other party or nonparty and its separate conduct, is diffuse and difficult to quantify. That is even further confirmation that causation, if any, is too remote. *Chase*, 2013 WL 1183332, at *5 (noting that "difficult to calculate" damages are sign of remote cause). "[T]he less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors." *Holmes*, 503 U.S. at 269. There is no feasible way

to measure how much any given Defendants' dispensing contributed to the "increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's community." Dkt. 3327 ¶ 626 (Track 3 Supplemental and Amended Allegations). All these alleged harms "could have been caused by many other factors unconnected to [Defendants'] conduct," *Ameriquest*, 615 F.3d at 504, including the conduct that this Court already held was directly connected to those harms, *see* 2018 WL 6628898, at *5.[4]

Second, Plaintiffs' chain of causation is further attenuated by several independent, criminal causes of Plaintiffs' injuries. For example, Plaintiffs' expert Dr. Keyes testified that illicit opioids, including heroin, fentanyl, and counterfeit pills (largely trafficked into the United States from China and Mexico) independently contributed to the burden in Lake and Trumbull Counties. *See, e.g.*, Dkt. 4065 at 89–93 (Oct. 22 trial tr., vol. 14). Some of these criminal acts actually *intervened* in the alleged causal chain between Defendants' conduct and Plaintiffs' alleged harms. *See Cascone v. Herb Kay Co.*, 451 N.E.2d 815, 819–20 (Ohio 1983); *see also* Dkt. 497-1 at 28–29. For example, Dr. Keyes agreed that "doctor shoppers," "medicine cabinet diversion," and theft all played a role in causing the overdose burden in Plaintiffs' Counties. Dkt. 4065 at 93–94 (Oct. 22 trial tr., vol. 14); Dkt. 4090 at 62 (Oct. 26 trial tr., vol. 16) (Keyes

[4] Plaintiffs are wrong if they claim that *Beretta* somehow helps them overcome these problems. For one thing, both the Ohio General Assembly (through the Ohio Products Liability Act, Ohio Rev. Code Ann. § 2305.10) and the U.S. Congress (through the Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, 119 Stat. 2095 (2005) (codified at 15 U.S.C. §§ 7901–03)) abandoned this case as an undue expansion of nuisance doctrine. For another thing, "[t]he involvement of so many independent actors also reveals why [Plaintiffs'] reliance on *Beretta* is misplaced." *Ameriquest*, 615 F.3d at 505. "*Beretta* has key differences"—chief among them that "through the direct action of the gun manufacturers" sued in *Beretta, and no one else*, "a black market for the illegal sale and distribution of firearms" allegedly existed. *Chase*, 2013 WL 1183332, at *6. Defendants' pharmacies, on the other hand, did not by themselves "create the cocktail of factors that led to" the opioid crisis. *Id.*; *see Ameriquest*, 615 F.3d at 505 (limiting *Beretta*). Thus, Plaintiffs have not proved and cannot prove that any damages they have suffered were proximately caused by any Defendant's dispensing conduct.

testifying there is "an extraordinary amount of unused opioids"); Dkt. 4064 at 220 (Oct. 21 trial tr., vol. 13) (Dr. Alexander agreeing that "70 percent of people who report nonmedical use of prescription opioids state their most recently used drug came from a friend or family member"); Dkt 4093 at 63–64 (Oct. 27 trial tr., vol. 17) (Lake County addiction official Kim Fraser agreeing that "excess pills in medicine cabinets [of] friends, family, visitors" contributed to the crisis). Those criminal acts severed any causal chain between Defendants' conduct and Plaintiffs' alleged harm.

Third, the prescribing behavior of medical professionals was yet another independent cause of Plaintiffs' alleged harm. Plaintiffs' dispensing theory rests on an alleged causal chain that involves the conduct of prescribing doctors and other medical professionals, who—if improper prescriptions were in fact presented to Defendants' pharmacies—necessarily violated the CSA before Defendants allegedly did. *See* 21 C.F.R. § 1306.04(a) (placing the "responsibility for the proper prescribing and dispensing of controlled substances" on "the prescribing practitioner"). Indeed, Dr. Keyes herself agreed that the opioid crisis would not have occurred if prescribing opioids had not become the standard medical practice for managing pain in patients. Dkt. 4065 at 98 (Oct. 22 trial tr., vol. 14).

Defendants and their pharmacists appropriately relied on prescribing medical professionals to evaluate manufacturers' marketing and set the standard of care. Without knowledge of illicit behavior—and there has been no evidence of any such knowledge in this case—Defendants' pharmacists "reasonably assume[d] that the physician will exercise his informed judgment in the patient's best interests." *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878–79 (Ohio 1991); *see, e.g.*, *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 596 (S.D. Ohio 2003) (dismissing

claim against opioid manufacturers on this basis). Defendants thus cannot be liable as a matter of law for Plaintiffs' dispensing claims.

C. Plaintiffs Have Not Adduced Legally Sufficient Evidence of Intentional and Culpable Conduct.

The Court should only instruct the jury that it may find Defendants liable for either intentional or unlawful conduct if it first finds there is sufficient evidence that Defendants engaged in *intentional* but *lawful* conduct. After all, any theory premised on intentional conduct *prohibited* by the CSA is already captured by the unlawfulness prong. But Plaintiffs have not presented any evidence that any Defendant, through conduct *permitted* by the CSA, "intended to act and knew, or was substantially certain, that the circumstances resulting from that act would interfere with public health or public safety." *See* Dkt. 3975-5 at 22 (final jury instruction on intentional conduct). The Court should therefore grant judgment in favor of Defendants on the intentional prong of absolute public nuisance and remove any reference to it from the jury instructions and jury verdict form.

a. Throughout this litigation, Plaintiffs have focused their case on proving that Defendants acted unlawfully by violating the CSA through distribution and/or dispensing. *See, e.g.*, Dkt. 3366 at 18–34 (Plaintiffs' Opposition to Pharmacy Defendants' Motion to Dismiss). Plaintiffs' theory at trial remains the same, though now focused on dispensing. *See, e.g.*, Dkt. 3991 at 48, 52, 54 (Oct. 4 trial tr., vol. 1). Thus, Plaintiffs' theory of the case depends on their ability to prove a violation of the CSA.

b. That Plaintiffs have consistently pressed this theory is not surprising, as any other strategy by them would present several insurmountable legal difficulties. For one thing, a theory of the case that sought to penalize Defendants for dispensing or distribution conduct that complied with the CSA would "stand[] as an obstacle to the accomplishment and execution of the full

purposes and objectives of Congress" and thus would be preempted by federal law. *Arizona v. United States*, 567 U.S. 387, 399–400 (2012); *see infra* Section II.C.3. Holding Defendants liable under Ohio public nuisance law for dispensing or distribution conduct that Congress considered and allowed under the CSA would "skew" the "delicate balance of statutory objectives" set by the Act: ensuring the availability of medically indicated therapeutics while, at the same time, limiting the improper use of controlled substances. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Nor would Ohio public nuisance law itself allow for such second-guessing of federal policy. A nuisance is an unreasonable interference with a public right. Under Ohio law, an interference with a public right is "unreasonable" only if Plaintiffs prove that the gravity of their harm outweighs the utility of Defendants' conduct, which involves evaluating the "social value" of such conduct. 1 Ohio Jury Instructions CV 621.05(4), (6). Here, Congress already has considered the distribution and dispensing conduct permitted by the CSA and determined that the social utility of the conduct outweighs the risk of harm. Conduct that is fairly encompassed within the scope of the CSA, and permitted by it, thus cannot be "unreasonable" as a matter of Ohio law.

For this reason, no "actionable" claim for public nuisance lies where "a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct exist." *Brown v. Cnty. Comm'rs. of Scioto Cty.*, 622 N.E.2d 1153, 1158–60 (Ohio Ct. App. 1993). Thus, duly licensed individuals who engage in extensively regulated activities cannot be held liable for absolute public nuisance. *State ex rel. Schoener v. Bd. of Cnty. Comm'rs of Hamilton Cty.*, 619 N.E.2d 2, 6 (Ohio Ct. App. 1992) (dismissing the absolute public nuisance claim and noting that "we think it [is] fair to say in law that part of the *quid pro quo* for the submission to such exacting regulatory oversight is the operator's insulation from liability under a theory of strict liability").

Thus, any attempt to argue that Defendants should still be held liable even though they have complied with the mandates of the CSA would not be viable.

As Defendants will separately set forth in their individual Rule 50(a) briefs, Plaintiffs failed in each of their attempts to adduce evidence of intentional and culpable conduct that is not regulated by the CSA and allegedly created oversupply and diversion of prescription opioid medications in Plaintiffs' communities. Therefore, the Court should grant Defendants judgment as a matter of law on the intentional prong of the absolute-nuisance test.

II. PLAINTIFFS' NUISANCE CLAIM FAILS AS A MATTER OF LAW.

Defendants have offered several reasons why Plaintiffs' claims are legally deficient, regardless of the evidence they produce at trial—which, by definition, means Plaintiffs cannot provide a legally sufficient evidentiary basis for their claims. Although the Court has rejected each of these arguments, *see* Dkt. 1032 (Order Denying Track 1B Motions to Dismiss); Dkt. 3403 (Order Denying Pharmacy Defendants' Track 3 Motion to Dismiss), Defendants restate them here to preserve them for appeal.

A. Ohio Statutory Law Precludes Plaintiffs' Common-Law Nuisance Suit.

Ohio law does not permit a common-law public-nuisance claim based on a distributor's or pharmacy's alleged failure to detect and prevent the diversion of drugs of abuse.

1. The Ohio Product Liability Act expressly bars Plaintiffs' nuisance claim. This bar includes "public nuisance claim[s] . . . in which it is alleged that the . . . supply, . . . distribution, . . . or sale of a product unreasonably interferes with a right common to the general public." Ohio Rev. Code Ann. § 2307.71(A)(13). Plaintiffs' suit here is just such a barred claim. This Court erred by earlier concluding that Plaintiffs are asserting a non-abrogated claim for equitable relief: among other reasons, the "abatement" Plaintiffs seek is the payment of billions of dollars, some of it for backward-looking damages. *See* Dkt. 491-1 at 35–39.

2. Ohio also comprehensively regulates controlled substances, including by providing the specific path (with specific remedies) to pursue for public-nuisance suits related to either distributing or dispensing controlled substances. The relevant statute, Ohio Rev. Code Ann. § 4729.35, permits lawsuits against pharmacies and distributors based on the allegedly unlawful manner of selling controlled substances—but exclusively in the manner specified by the statute, including, most notably here, only for an injunction. Plaintiffs purport to ground their nuisance claim in common law rather than this statute. But Ohio law does not permit a plaintiff to bring a common-law claim where, as here, the Ohio legislature has comprehensively regulated the field and provided specific remedies that conflict with the common-law cause of action. *See Thompson v. Ford*, 128 N.E.2d 111, 115–16 (Ohio 1955); *Bolles v. Toledo Tr. Co*., 58 N.E.2d 381, 392 (Ohio 1944); *see also* Dkt. 3340-1 at 13–19. Plaintiffs' claim is thus precluded.

B. Ohio Common Law Precludes Plaintiffs' Public-Nuisance Suit.

Even as a matter of common law, Plaintiffs' theory is not viable. Defendants owe no duty to Plaintiffs for their distribution and dispensing conduct under Ohio nuisance law.

1. *Plaintiffs cannot show the violation of a public right*. "To recover damages under a claim of public nuisance, the plaintiff must establish," among other things, "an interference with a public right." *Kramer v. Angel's Path, L.L.C*, 882 N.E.2d 46, 52 (Ohio Ct. App. 2007). But there is no common law "public right to be free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a manner that may create a risk of harm to another." *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004). Put differently, the right not to be negligently injured by a product or by another person's misuse of a product is a *private* right, not a public right. *See Kramer*, 882 N.E.2d at 52 ("A public nuisance will not arise because a large number of people are affected; rather, it arises only when a public right has been affected."); Restatement (Second) of Torts

§ 821B cmt. g (1979) (same, comparing to "the individual right that everyone has not to be assaulted . . . or negligently injured"). Plaintiffs accordingly cannot base their public-nuisance claim on the private misuse of opioid medications and are thus unable to prove the invasion of a public right. *See* Dkt. 491-1 at 39–42; Dkt. 497-1 at 27; Dkt. 3340-1 at 37.

2. *Plaintiffs cannot show that Defendants' highly regulated dispensing and distribution conduct constitutes a nuisance*. Plaintiffs cannot base their nuisance claim on Defendants' highly regulated distribution and dispensing conduct. *See* Dkt. 491-1 at 42–43; Dkt. 497-1 at 26–27; Dkt. 3340-1 at 37.

An absolute nuisance ordinarily involves an inherently dangerous activity "that cannot be maintained without injury to property, no matter what precautions are taken." *Kramer*, 882 N.E.2d at 52. But Plaintiffs' entire theory of the case at trial is that opioids *can* be distributed safely, and that Defendants can be faulted for not doing so. And irrespective of Plaintiffs' view, the fact is that distributing and dispensing prescription opioid medications remains authorized, yet extensively regulated, by state and federal law for extremely important public policy reasons. No "actionable" nuisance tort lies where, as here, "a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct exist." *Brown*, 622 N.E.2d at 1158–60; 39 Am. Jur., Nuisances, § 8 (stating that public nuisances always arise out of unlawful acts, and that which is lawful, or is authorized by a valid statute, or which the public convenience imperatively demands, cannot be a public nuisance).

3. *Defendants have no control over the opioid medications at the time of the alleged nuisance.* This Court cannot expand Ohio's common law by eliminating the traditional "control" element of a nuisance claim—an element Plaintiffs did not allege and cannot prove.

Ohio public nuisance law has long contained a control element. *See, e.g.*, *Kramer*, 882 N.E.2d at 56 (no nuisance "absent any evidence of such a right of possession or control" because the defendant then "has no ability to create or prevent [the] nuisance"); *see also Taylor v. City of Cincinnati*, 55 N.E.2d 724, 725 (Ohio 1944) (syllabus ¶ 2, defining the traditional elements of "absolute nuisance" to include the defendant's "control or direction" of the supposedly nuisance-causing land or instrumentality). The control element makes sense because "the principal remedy for the harm caused by the nuisance is abatement," and the defendant cannot abate a nuisance if it no longer has control over what created it. *State v. Lead Indus. Ass'n*, 951 A.2d 428, 449 (R.I. 2008). Other plaintiffs' failures to satisfy this element have led to dismissals of many similar lawsuits. *See, e.g.*, *City of Manchester v. Nat'l Gypsum Co.*, 637 F. Supp. 646, 656 (D.R.I. 1986) (asbestos manufacturers not liable in nuisance after they relinquished control over the asbestos); *Lead Indus*., 951 A.2d at 449 (paint manufacturers not liable in nuisance when they lack "control over the [paint] . . . *at the time the damage occurs*"). This even includes a case involving opioids: A "defendant is not liable for public nuisance unless it exercises control over the instrumentality that caused the nuisance *at the time of the nuisance*," and thus opioids plaintiffs cannot show "control by [d]efendants over the instrumentality [opioids] at the time of the [alleged] nuisance"—i.e., when third parties diverted the opioids and used them illegally. *State ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382, at *13 (Del. Super. Ct. Feb. 4, 2019).

This Court, sitting in diversity, may not abolish or expand the control element. *See Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004). It thus may not hold pharmacies liable for the supposed nuisance created after the opioids left their control. The evidence submitted at trial shows that any effects of the nuisance did not occur while opioids were behind the counter in a

pharmacy. Instead, they occurred only *after* the drugs were dispensed—that is, *after* they left Defendants' control.

4. *The CSA and its Ohio analog are not predicate "safety statutes."* Plaintiffs also cannot prove the violation of a "safety statute," as required to prove liability under the "unlawful" prong of absolute nuisance. *See* 1 Ohio Jury Instructions CV 621.01; Dkt. 3449 at 81 n.49 (Defendants' Track 1B proposed jury instructions). A statute is a "safety statute" only if it sets forth a "*specific* legal requirement for the protection of others[.]" *Taylor*, 55 N.E.2d at 728 (emphasis added). In that sense a claim for absolute public nuisance based on a violation of a safety statute resembles a private plaintiff's claim for negligence *per se*. *Uland v. S.E. Johnson Co.*, No. WM-97-005, 1998 WL 123086, at *5 (Ohio Ct. App. Mar. 13, 1998) (liability for an absolute nuisance based on the violation of a safety statute is equivalent to liability for negligence *per se*).

Plaintiffs' absolute nuisance claim rests on regulatory violations of the CSA, but those provisions and their Ohio analogs are *not* safety statutes because they contain no private right of action. *See Smrtka v. Boote*, 88 N.E.3d 465, 474 (Ohio Ct. App. 2017) ("A negligence *per se* claim is not appropriate when 'the legislative enactment in question does not define a civil liability but instead only makes provision to secure the safety or welfare of the public.'") (quoting *Moreland v. Oak Creek OB/GYN, Inc.*, 970 N.E.2d 455, 462 (Ohio Ct. App. 2005)); *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290–91 (D. Colo. 2016). And the violation of *regulations* interpreting the CSA is insufficient for *per se* liability. *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 202–03 (Ohio 1998) (noting that "to bestow upon administrative agencies the ability to propose and adopt rules that alter the proof requirements between litigants 'would be tantamount to an unconstitutional delegation of legislative authority, since administrative agencies cannot dictate public policy'"). Finally, the jury would need to make more than a single finding of fact to

determine whether the alleged distribution and dispensing duties at issue here were violated. *See* Dkt. 2483 at 29 (suspicious order duties would require multiple findings of fact); *Becker v. Shaull*, 584 N.E.2d 684, 685–87 (Ohio 1992) (no negligence *per se* when the jury would be required to make multiple findings of fact).

5. *Plaintiffs seek an unprecedented expansion of nuisance contrary to public policy*. Plaintiffs' product-based nuisance theory also must be rejected on public-policy grounds and as an illegitimate expansion of Ohio common law. *See* Dkt. 491-1 at 35–39 (Distributor Defendants' Track 1B Motion to Dismiss). Plaintiffs' suit is unprecedented: No Ohio court (and no federal court applying Ohio law) has ever permitted a political subdivision to bring a nuisance-based product-liability action on behalf of its residents, and certainly not to claim that an abstract and complicated public health issue such as the opioid epidemic is a "nuisance" that the county must be paid to "abate." *See Ameriquest*, 615 F.3d at 506. It cannot be that any product that poses any health or safety risks to the user or public can create billions of dollars of nuisance liability to compensate for any harm that might have resulted from an end-user's misuse of the product. *See Tioga Pub. Sch. Dist. No. 15 of Williams Cnty. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993) (stating that if law recognized products-based nuisance claims, "[n]uisance . . . would become a monster that would devour in one gulp the entire law of tort"); *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 521 (Mich. Ct. App. 1992) (concluding that allowing product-based nuisance claims "would significantly expand, with unpredictable consequences, the remedies already available to persons injured by products").

Absent Ohio cases expanding the common law in this way, this Court has no authority to do so. *See Berrington v. Wal-Mart Stores, Inc.*, 696 F.3d 604, 610 (6th Cir. 2012). "[W]hen given a choice between an interpretation of state law which reasonably restricts liability, and one which

greatly expands liability," federal courts sitting in diversity "should choose the narrower and more reasonable path." *Combs*, 354 F.3d at 577. They should be "extremely cautious about adopting 'substantive innovation' in state law" and should not endorse "fundamental policy innovation[s]" when the State has not already done so. *Id.* at 578. Charting this narrower path here means Plaintiffs' novel theory must fail.

C. Defendants Owe No Duty to Plaintiffs for Their Distribution and Dispensing Conduct Under the CSA or Its Ohio Analog.

Under the CSA, Defendants owe no corporate-level duty to Plaintiffs for their distribution and dispensing conduct. Even if such a regulatory duty existed, Defendants would not owe it to Plaintiffs. In any event, the CSA preempts Plaintiffs' claims and contains no private right of action.

1. *Defendants did not owe the corporate-level dispensing duties on which Plaintiffs base their nuisance claim*. Plaintiffs' public-nuisance claim fails as to dispensing because they cannot point to any provision of the CSA or its related regulations that Defendants violated. *See* Dkt. 3340-1 at 20–26 (Pharmacy Defendants' Track 3 Motion to Dismiss). The CSA and relevant state regulations require only that Defendants comply with certain specified physical-security, recordkeeping, and licensing requirements—requirements everybody agrees Defendants have satisfied. Most critically, Plaintiffs did not produce a shred of evidence to suggest that Defendants employed unlicensed pharmacists. *See* 21 C.F.R. § 1306.06. Nor did they show that Defendants' pharmacists (let alone those in Plaintiffs' Counties) knowingly filled even a single prescription that was not prescribed in the usual course of professional treatment. *Id.* § 1306.04(a).

That should be the end of the case. Any CSA-related duties must derive from the CSA's text or its regulations, not from guidance documents, DEA administrative rulings regarding licensing revocations, or anything else. Plaintiffs nonetheless argue that Defendants violated the

CSA, at the corporate level, by not alerting their pharmacists to certain "red flags" and requiring them to resolve such flags through documentation. But the obligation to evaluate a prescription and guard against dispensing-based diversion resides not at the corporate level but with the individual pharmacist presented with a prescription. The regulation could not be clearer: "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with *the pharmacist who fills the prescription*." *Id.* § 1306.04(a) (emphasis added); *see also* Ohio Admin. Code § 4729-5-21(A) (same); Ohio Admin. Code § 4729-5-30(A) (same). The regulatory text assigns primary responsibility for ensuring the proper prescribing and dispensing of controlled substances to the doctor or other prescriber and a "corresponding" responsibility to the "pharmacist" who fills the prescription.

Resisting this plain text, Plaintiffs cite 21 C.F.R. § 1301.71(a), which requires all registrants (including pharmacies) to provide effective controls to guard against the theft and diversion of controlled substances. But for pharmacies, this regulation imposes only requirements for in-store physical security controls and has never been understood to require a "system" for monitoring prescriptions and disclosing "suspicious orders of controlled substances," *id.* § 1301.74(a)–(b) (applying this "system" requirement only to distributors of controlled substances); *see also, e.g.*, *ChipRX, L.L.C., d/b/a City Center Pharmacy*; *Decision and Order*, 82 Fed. Reg. 51,433-02, 51,434 (Nov. 6, 2017) (finding that the pharmacy was alleged to have failed to maintain effective controls against diversion and theft because the pharmacist-in-charge was routinely stealing controlled substances to fuel his own addiction and deleting surveillance video footage of his unlawful removal of controlled substances from the pharmacy premises).

Like Ohio law, DEA regulations define "pharmacist" as a state-licensed professional *individual*, not a pharmacy corporation. 21 C.F.R. § 1300.01; Ohio Admin. Code § 4729:1-1-01(M). The regulation's description of a pharmacist's responsibility as "corresponding" to the responsibility of the "prescribing practitioner" reinforces that the obligation rests with the pharmacist, not the corporate owner. These responsibilities are *professional* in nature—demanding the exercise of specialized judgment by a professional who has earned the required degree and is trained and licensed in a regulated discipline.

Altogether, Plaintiffs' novel theory that Defendants had a corporate-level duty to enact specific systems, policies, or procedures to prevent improper dispensing cannot be reconciled with the sources of law on which Plaintiffs rely. *See* Dkt. 3499 at 7 ("[T]here is no absolute requirement, for example, that a pharmacy must conduct a computerized red-flag analysis of each prescription before filling it."). And even if such a regulatory duty existed, it would not be owed to Plaintiffs.

2. *Defendants did not owe the corporate-level distribution duties on which Plaintiffs base their nuisance claim*. As for distribution, Plaintiffs argue that, as controlled-substance distributors, Defendants were required to investigate and clear "suspicious" orders before distributing them. But as DEA's newly proposed regulations show, Defendants had no such duty under the law that existed at the time they self-distributed. Instead, they were required only to *report* "suspicious" orders to DEA, which could then investigate as necessary. 21 U.S.C. § 823(a); 21 C.F.R. § 1301.74(b).

In recently seeking to promulgate new regulations to restrict the shipment of "suspicious" orders, DEA has confirmed that its existing regulations do not impose such restrictions. *See Suspicious Orders of Controlled Substances*, 85 Fed. Reg. 69,282, 69,298 (proposed Nov. 2, 2020)

(to be codified at 21 C.F.R. at 1301). DEA proposes these changes to implement the Preventing Drug Diversion Act of 2018, which amended the CSA to more closely regulate drug distribution. *Id.* at 69,282.[5] Under the proposed rule, a registrant who receives a "suspicious" order would have two options: It may "decline to distribute pursuant to the suspicious order, immediately file a suspicious order report through DEA centralized database [], and maintain a record of the suspicious order and any due diligence related to the suspicious order." *Id.* Or it can "conduct due diligence to investigate each suspicious circumstance" and, if able to dispel each such circumstance within seven days, "distribute pursuant to the order" and "maintain a record of its due diligence." *Id.* at 69,298–99. DEA is thus proposing to "amend[] its regulations," *id.* at 69288, to establish the no-ship obligation that Plaintiffs imagine has always existed. *See Hiivala v. Wood*, 195 F.3d 1098, 1103 (9th Cir. 1999) ("When Congress alters the wording of a statute, we presume that Congress intended a change in the law."). If the existing regulations had already imposed a no-ship duty, there would be no need for DEA to seek to amend its regulations to add such a duty.

Lastly, this case differs meaningfully from *Southwood Pharmaceuticals Inc.*; *Revocation of Registration*, 72 Fed. Reg. 36,487, 36,501 (July 3, 2007), and *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017), on which this Court has relied in the past to infer a no-ship duty. *See* Dkt. 2483. In each of those cases, the registrant was distributing to several external and suspicious pharmacies. As soon as the registrant distributed the controlled substance, the registrant lost control of the controlled substance. Here, part of what made Defendants' controls "effective" under the CSA was that they distributed only to themselves. As a result, Defendants retained control even after the distribution occurred, up until the point at

[5] More specifically, this legislation "replaced DEA Field Division Office reporting with centralized reporting to DEA Headquarters," causing DEA to revisit its suspicious order reporting protocol. 85 Fed. Reg. at 69,286 n.45.

which the drugs were dispensed. This Court's imposition of a "no-shipment" duty as to self-distributors is thus unprecedented.

3. *Penalizing Defendants for dispensing or distribution conduct that does not violate the CSA would stand as an obstacle to Congress's objectives and is thus preempted.* Any theory of the case that seeks to penalize Defendants for dispensing or distribution conduct that *does not violate* the CSA would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and thus be preempted by federal law. *Arizona*, 567 U.S. at 399–400. Congress enacted the CSA to "control the supply and demand of controlled substances," *Gonzales v. Raich*, 545 U.S. 1, 19 (2005). In doing so, Congress sought to balance two related concerns. Many regulated drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). But "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." *Id.* § 801(2).

The Act's regulatory scheme is designed to strike a balance between "foster[ing] the beneficial use of those medications" while also "prevent[ing] their misuse[.]" *Raich*, 545 U.S. at 24. Congress vested DEA with the authority to promulgate regulations (through notice-and-comment rulemaking) and to enforce the statute with both these considerations in mind. Holding Defendants liable for dispensing or distribution conduct under Ohio nuisance law that Congress considered and allowed under the CSA would thus "skew" the "delicate balance of statutory objectives" set by federal law. *Buckman Co.*, 531 U.S. at 348.

Plaintiffs' common law tort theory is also preempted because it would also interfere with the discretion Congress gave DEA. *See Raich*, 545 U.S. at 19 (CSA covers and preempts the field

of controlled substances). The CSA grants DEA with the authority to determine whether it is inconsistent with the public interest to allow an entity to distribute or dispense controlled substances, which includes DEA's assessment of whether a distributor has "effective controls" against diversion. *See* 21 U.S.C. § 823(b). Once DEA approves a registration, the pharmacy is "*authorized* to [] distribute[] or dispense controlled substances." *Id.* § 822(b) (emphasis added). Plaintiffs, however, seek to hold Defendants liable for exactly what DEA has "authorized" and thereby leverage Ohio nuisance law to second-guess the judgment of the expert federal agency Congress tasked with making the relevant judgment. Plaintiffs themselves have even acknowledged that any claims based on conduct that complied with the CSA would be preempted. *See* Dkt. 3464 at 29 ("The point is that the Pharmacy Defendants **did not** comply with the CSA when distributing their opioid products. There is no preemption issue. . . ." (emphasis in original)). But it is up to DEA, not a jury, to determine whether registration of a distributor or pharmacist is in the public interest.

Indeed, DEA is permitted "to maintain and not revoke the registration of a registrant despite violations of the CSA," so long as the registrant substantially complies with the law. *See* Dkt. 4075 (Plaintiffs' proposed jury instruction); 21 C.F.R. § 1301.71(b). DEA is even granted broad discretion to waive the registration requirement altogether, so long as it is "consistent with the public health and safety." 21 U.S.C. § 822(d). Time and time again, the CSA grants DEA discretion over what conduct suffices and does not suffice to warrant registration and, along with it, authorization to distribute or dispense controlled substances. Plaintiffs' lawsuit completely removes DEA from this equation, asking a lay jury to decide for themselves what is authorized and what is not in the first instance. Such an approach is plainly inconsistent with the text and design of the CSA.

Plaintiffs' theory also offends due process. The imposition of common law tort liability is an exercise of state power that must comply with the "fair notice" requirements of due process. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996). Plaintiffs cannot use a tort lawsuit either to retroactively change the regulations under which Defendants were "authorized" to operate or to retroactively overturn its record of compliance with those regulations. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992) (noting that a "state regulation can be as effectively exerted through an award of damages as through some form of [preventative] relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy"). Plaintiffs' attempt to retroactively re-regulate Defendants usurps the role of the regulator and encourages standardless, arbitrary, and contradictory enforcement of comprehensive regulations by private litigants.

4. *The CSA does not give Plaintiffs a private right of action to sue Defendants even for distribution or dispensing conduct that does violate the Act.* DEA's enforcement authority is exclusive, precluding private suits. The agency's regulations elaborating on "effective controls against diversion" sets the criteria for *DEA* to use to license distributors and dispensers of controlled substances; they do not impose duties that *municipalities* can enforce in a common-law suit. *See* Dkt. 491-1 at 48–56; Dkt. 497-1 at 18–21; Dkt. 3340-1 at 36. Courts recognize that "according to its plain terms, 'the CSA is a statute enforceable only by the Attorney General and, by delegation, the Department of Justice.'" *Hickenlooper*, 164 F. Supp. 3d at 1290 (quoting *Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 293 (3d Cir. 2010) (per curiam)), *aff'd sub nom. Safe Sts. All. v. Hickenlooper*, 859 F.3d 865 (10th Cir. 2017).

As a result, federal courts—including in opioid cases—"have uniformly held that the [federal] CSA does not create a private right of action." *E.g.*, *Smith*, 164 F. Supp. 3d at 1290;

Memorandum Opinion and Order at 14–15, *West Virginia v. McKesson Corp.*, No. 17-cv-03555, 14–15 (S.D. W. Va. Feb. 15, 2018); *McKesson Corp. v. Hembree*, No. 17-cv-323, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018). Plaintiffs' efforts to enforce statutory and regulatory duties through common-law nuisance "would, in effect, be permitting a private cause of action under" the statute or regulation and should not be allowed. *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994). Thus, regardless of whether Plaintiffs are right about what corporate-level duties Defendants had under the CSA, Plaintiffs have no legal right to enforce them.

5. *Plaintiffs' claims are barred by the primary jurisdiction doctrine.* For reasons similar to why Plaintiffs' claims are preempted by the CSA, those claims are also barred by the primary jurisdiction doctrine. Under that doctrine, federal courts refrain from adjudicating claims that require resolution of issues within the "special competence" of a federal agency. *Charvat v. EchoStar Satellite, LLC*, 630 F.3d 459, 466 (6th Cir. 2010). A court should leave an issue to an agency "for a variety of reasons: (1) to advance regulatory uniformity; (2) to answer a 'question . . . within the agency's discretion'; and (3) to benefit from 'technical or policy considerations within the agency's . . . expertise.'" *Id.* (internal citations omitted). These reasons require this Court to leave the question of whether Defendants have complied with the CSA to DEA. After all, Congress entrusted DEA alone with broad discretion to enforce the CSA uniformly by balancing the regulatory scheme's goals of "foster[ing] the beneficial use of . . . medications[,]" while "prevent[ing] their misuse." *Raich*, 545 U.S. at 24.

D. Plaintiffs' Nuisance Claim Fails for Additional Legal Reasons.

1. *Standing.* Plaintiffs lack standing—both of the prudential (public-nuisance) and Article III variety. Public-nuisance claims fail on remoteness grounds either if there is no "direct relationship between [Plaintiffs'] harm and Defendants' conduct" (causation, *supra* Sections I.A.2 and I.B.2), or if the harm "is wholly derivative of the harm suffered by a third party" ("prudential

standing"). *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 621 F. Supp. 2d 513, 532 (N.D. Ohio 2009), *aff'd*, 615 F.3d 496. Plaintiffs lack prudential standing because their alleged injuries are wholly derivative of the harm suffered by third parties: the Counties' residents. *See, e.g.*, *id.*; *Laborers Loc. 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 235 (2d Cir. 1999); *see also* Dkt. 497-1 at 23; Dkt. 491-1 at 58–62. And Plaintiffs lack Article III standing to sue for indirect injuries incurred in the first instance by others. *See Coyne v. Am. Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999); *see also* Dkt. 497-1 at 11–14, Dkt. 3340-1 at 36.

Moreover, as the Supreme Court recently underscored in *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021), Article III does not permit Plaintiffs to regulate mere regulatory non-compliance. "Federal courts do not possess a roving commission to publicly opine on every legal question," nor do they "exercise general legal oversight . . . of private entities." *Id.* at 2203. Like other plaintiffs, the counties "are not charged with pursuing the public interest in enforcing a defendant's general compliance with regulatory law." *Id.* at 2207. Congress instead tasked DEA with that responsibility. It is thus insufficient for Plaintiffs to rely on regulatory noncompliance, or an allegedly increased risk of harm stemming from regulatory noncompliance, as a basis for Article III standing. *Id.* at 2211.

2. *Economic Loss Doctrine*. The economic loss doctrine bars Plaintiffs' claim. *See* Dkt. 491-1 at 56–57, Dkt. 3340-1 at 36. "The doctrine bars tort plaintiffs from recovering purely economic loss that does not arise from tangible physical injury to persons or property." *Deutsche Bank*, 863 F.3d at 477 (cleaned up); *see id.* at 477–78 (collecting cases). A "claim of absolute nuisance [thus] requires that the plaintiff sustain injury to property"—its own person or property—and Plaintiffs have not shown (or even alleged) that here. *RWP, Inc. v. Fabrizi Trucking & Paving*

Co., No. 87382, 2006 WL 2777159, at *4 (Ohio Ct. App. Sept. 28, 2006); *see, e.g.*, *Ameriquest*, 621 F. Supp. 2d at 522–26.

Contrary to this Court's pretrial conclusion, there is no persuasive indication in Ohio law that the economic loss rule does not apply, or applies differently, to claims of absolute public nuisance like the one at issue here. The decision in *Eysoldt* v. *ProScan Imaging*, 957 N.E.2d 780 (Ohio Ct. App. 2011), was not a nuisance case; it considered claims for conversion and invasion of privacy when the defendant website hosting company had a direct relationship with the plaintiffs, who were customers. No such relationship between Plaintiffs and Defendants exists here. Any liability would arise from an underlying contractual relationship between Defendants and their customers, not from a direct duty or special relationship between Plaintiffs and Defendants. *See also* Restatement (Third) of Torts: Liab. for Econ. Harm § 8 cmt. g (2020) (generally no liability in public nuisance for economic harm caused by products).

3. *Statewide Concern Doctrine*. Plaintiffs' claims are also barred and preempted by the statewide concern doctrine. *See* Dkt. 491-1 at 57–58, Dkt. 3340-1 at 36. Simply put, "[i]t is a fundamental principle of Ohio law that, pursuant to the 'statewide concern' doctrine, a municipality may not, in the regulation of local matters, infringe on matters of general and statewide concern." *Am. Fin. Servs. Ass'n v. City of Cleveland*, 858 N.E.2d 776, 781 (Ohio 2006). The municipality Plaintiffs here attempt to regulate and infringe upon a matter of the most general concern. *See Chase*, 2013 WL 1183332, at *6 (action for "money judgment stemming from common-law suits may constitute regulation"); *Ameriquest*, 621 F. Supp. 2d at 518 ("Without question, common law actions for damages represent an important manner of regulating conduct."). Ohio courts would not allow it, and neither may this Court.

4. *Municipal cost recovery rule*. This rule, also known as the free public services doctrine, further bars Plaintiffs' claims. Under this doctrine, "public expenditures made in the performance of governmental functions"—like those allegedly spent by Plaintiffs here—"are not recoverable in tort." *Beretta*, 821 N.E.2d at 1144. Decisions over how and whether to allocate certain costs, including the costs to address the opioid crisis, "necessarily implicate[] fiscal policy, a matter best left to the legislature and its public deliberative processes, rather than the court" (especially a federal court). *Walker Cnty. v. Tri-State Crematory*, 643 S.E.2d 324, 327 (Ga. Ct. App. 2007). This doctrine squarely applies, and no exceptions allow the suit to proceed.

5. *Statute of Limitations*. Plaintiffs' public-nuisance claim is barred by the two-year Ohio Product Liability Act ("OPLA") statute of limitations, Ohio Rev. Code § 2305.10, but even if OPLA does not apply, it is barred under the more general four-year statute of limitations for tort suits "[f]or an injury to the rights of the plaintiff not arising on contract," Ohio Rev. Code Ann. § 2305.09. *See, e.g.*, *Ashtabula River Corp. Grp. II v. Conrail, Inc.*, 549 F. Supp. 2d 981, 984 (N.D. Ohio 2008); *see also* Dkt. 1874; Dkt. 3340-1 at 36–37.

Under Ohio law, nuisances are either permanent or continuing. *Kramer,* 882 N.E.2d at 52; *see also Sexton v. Mason*, 883 N.E.2d 1013, 1021 (Ohio 2008); *Ashtabula River Corp.*, 549 F. Supp. 2d at 984; *Brown v. Whirlpool Corp.*, 996 F. Supp. 2d 623, 642–43 (N.D. Ohio 2014). "A continuing nuisance arises when the wrongdoer's tortious conduct is ongoing, perpetually generating new violations. Conversely, a permanent nuisance occurs when the wrongdoer's tortious act has been completed, but the plaintiff *continues to experience injury in the absence of any further activity by the defendant*." *Kramer*, 882 N.E.2d at 52 (emphasis added); *see also Sexton*, 883 N.E.2d at 1018 (explaining that "a permanent trespass occurs when the defendant's tortious act has been fully accomplished . . . [t]hat is, a trespass under Ohio law is a continuing

trespass only if the trespass itself, and not the ongoing injury or harm caused by a past, completed misdeed, is continuing") (citations and quotations omitted).

From their opening statement through the close of their case in chief, Plaintiffs have acknowledged that Defendants' alleged misconduct occurred years ago and is not continuing today. Plaintiffs' claims are based on indirect injuries from past conduct "in the absence of any further activity by the defendant," not on a continuing nuisance. As Plaintiffs' counsel stated in their opening:

> The problems folks face today is not something that happened because of bad policies yesterday. The bad policies go back into the 2000s; 1999 to 2010, '11, '12, '13, '14. And the problem with this is you get a lot of people addicted to some of these . . . prescription opiates, and then all of a sudden, you cut off the prescriptions, and that availability is not on the street, and they've got an opiate addiction. So at that point in time, they've got to seek out the illegal opiates.

Dkt. 3991 at 77 (Oct. 4 trial tr., vol. 1). The "illegal opiates" are chiefly illegal fentanyl and heroin, or other illegal drugs that Defendants have never distributed or dispensed.

Plaintiffs' evidence was consistent with their opening statement. Plaintiffs' evidence of distribution was virtually nonexistent, and they could have presented no evidence that Defendants distributed prescription opioids after April 9, 2014, for Walgreens; after October 2014 for CVS; and after April 2018 for Walmart. Although a witness mentioned ongoing prescription opioid abuse, Dkt. 4050 at 95–96 (Oct. 19, trial tr., vol. 11), he could not link it to any of the pharmacies, *Id.* at 96–97, and the bulk of Plaintiffs' evidence of ongoing abuse focused on illicit drugs. *See* Dkt. 4065 at 48–50 (Oct. 22, trial tr., vol. 14) (Dr. Keyes explaining the three phases of "opioid epidemic," with prescription opioids as the chief source in the late 1990s and early 2000s, then a shift occurring around 2010 toward heroin, and another shift in 2014 or 2015 to synthetic opioids including fentanyl); Dkt. 4050 at 62–65 (Oct. 19, trial tr., vol. 11) (noting current problems with

illicit fentanyl, cocaine, heroin, and methamphetamine, and counterfeit pills, as well as prescription opioids); *Id.* at 92–94; Dkt. 4065 at 92–93 (Oct. 22, trial tr., vol. 14) (discussing effects of illicit fentanyl). Although Plaintiffs contend that some prescriptions bore "red flags" into 2019, the bulk of their evidence of alleged improperly filled prescriptions occurred before 2014. *See* Dkt. 4026 at 185–186 (Oct. 14 trial tr. vol. 8).

Plaintiffs' evidence is intended to show, however implausibly, that they continue to incur *damages* from Defendants' conduct that ended years ago—that is, the prescription-opioid abuse led to illegal-narcotic abuse, and that illegal-narcotic abuse continues to cause damage to the counties when addicted persons put a strain on tax municipal services. But the principal drugs causing the current alleged damages are not distributed or dispensed by Defendants, and no evidence suggests that wrongfully dispensed prescription opioids are currently causing those damages. The evidence cannot show any continuing misconduct by Defendants and thus it cannot show a continuing public nuisance.[6]

Finally, Plaintiffs may not rely on any sort of tolling. This Court has established that equitable tolling does not apply. *See In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4194296, at *10–12 (N.D. Ohio Sept. 4, 2019) (rejecting equitable tolling). Neither does discovery-rule tolling apply to these kinds of claims, *see Inv'rs REIT One v. Jacobs*, 546 N.E.2d 206, 210 (Ohio 1989), nor would it provide relief anyway, *see Flowers v. Walker*, 589 N.E.2d 1284, 1287–88 (Ohio 1992). And, likewise, there is no evidence of fraudulent concealment, *see, e.g.*, *Perkins v. Falke & Dunphy, LLC*, No. 25162, 2012-Ohio-5799, 2012 WL 6097104, at *3

[6] By the same token, Plaintiffs are not entitled to abatement as a remedy. Plaintiffs' evidence suggests that the alleged nuisance at issue—an ostensible "oversupply" of prescription opioids by the Defendants—has been abated; i.e., Defendants' alleged misconduct has terminated, even if Plaintiffs' claimed damages from that misconduct continue to be incurred.

(Ohio Ct. App. 2012), and it would not bar the claims anyway, *Lutz v. Chesapeake Appalachia, LLC*, 717 F.3d 459, 475 (6th Cir. 2013); *see* Dkt. 1874 at 8–14.

In sum, Plaintiffs' claims accrued, and the limitations period began to run, when the allegedly wrongful conduct occurred (i.e., when the allegedly suspicious orders shipped or alleged illegitimate prescriptions were filled). *LGR Realty, Inc. v. Frank & London Ins. Agency*, 98 N.E.3d 241, 245 (Ohio 2018). The evidence Plaintiffs have introduced shows that all allegedly unlawful or intentional conduct that supposedly caused the nuisance occurred more than four years before the suits, which were filed on December 1 and December 11, 2017. Plaintiffs' claims are thus time-barred.[7]

6. *No Ongoing Nuisance of Prescription Opioids Requiring Abatement.* Plaintiffs have failed to show, as they must, an *ongoing* public nuisance. As previously explained, at most Plaintiffs have purported to show a current *illicit* opioid crisis, but their own evidence shows that Defendants only ever distributed or dispensed FDA-approved prescription opioids. *See, e.g.*, Dkt. 4005 at 49 (Lembke testimony, Oct. 7 trial tr., vol. 4) ("Q. And you understand that the FDA has approved prescription opioid medicines? A. Yes"); Dkt. 4023 at 105 (Rannazzisi testimony, Oct. 13 trial tr., vol. 7) ("Q. And in your testimony today, you have no evidence . . . that Walmart distributed prescription opioid medications in Lake or Trumbull Counties that were not approved by the FDA, are you? A. No, sir"); *see also* Dkt. 4090 at 125 (Oct. 26 trial tr., vol. 16) (Keyes testifying that if the FDA had not approved 21 different opioids, the opioid crisis would not exist). Plaintiffs argue that Defendants engaged in misconduct with respect to those prescription medications, and they claim that they continue to incur damages as a result of that misconduct.

[7] Alternatively, if there is some evidence showing that Plaintiffs did not discover their claims more than four years before the filing of the Complaints, or that some allegedly improper distribution or dispensing occurred within the limitations period, the jury must be instructed on the statute of limitations and Defendants must be given a fair opportunity to present evidence and argument relevant to the limitations.

But that is different from saying that a *prescription opioid* nuisance is ongoing, and Plaintiffs have not made that showing.

7. *Improper Expert Testimony.* Defendants preserve their objection to the admission of expert testimony from Dr. Caleb Alexander (Dkt. 3856-4), Carmen Catizone (Dkt. 3914-2), Dr. Katherine Keyes (Dkt. 3858-2), Dr. Anna Lembke (Dkt. 3915-2), and Craig McCann (Dkt. 3866-2). *See also* Dkt. 3794 (Preserving prior expert testimony objections). Without any one of their testimony, Plaintiffs' case is legally insufficient and fails as a matter of law. Among other objections, Defendants renew the following arguments:

- Dr. Alexander's expert opinions were primarily about abatement, which is only relevant at the remedial stage of this trial, Phase Two. Dkt 3856-4 at 3; *see* Dkt. 4064 at 231–35 (Oct. 21, trial tr., vol. 13) (Alexander testifying and explaining that to remediate the opioid crisis there must be: (1) an improvement in doctors' prescribing practices; (2) removal of unwanted medicine sitting in medicine cabinets; (3) reduction of opioids for nonmedical use; (4) decrease of dangerous combination of medicines; and (5) access to treatment medicines, like Buprenorphine to addicted individuals).

- Catizone's attempt to mechanistically identify "red flags" was unreliable, and he has made no attempt to test whether it actually identifies prescriptions that are likely to be diverted. Dkt. 3914-2 at 1; *see, e.g.*, Dkt. 4017 at 22, 24, 46–47, 61–63 (Oct. 12, trial tr., vol. 6) (Catizone testifying that when he analyzed the 2,000 prescription data, he made no attempt to identify and determine: (1) patients who needed to fill their prescriptions close to work versus where they lived; (2) patients who actually had insurance when they paid in cash; (3) the type of doctor prescribing the medication; and (4) the historical prescription data-monitoring systems and policies that were available by Defendants); *Id.* at 89 (Catizone further admitting that he did not apply the Government or DEA metrics in his analysis to determine the percentage of the medicines pharmacies dispensed to determine controlled substances versus no controlled substances and regular prescriptions).

- Dr. Keyes' causation opinions were not based on peer-reviewed literature, and have not been scientifically tested in any way. They are solely the product of Dr. Keyes' unsound reasoning, not any reliable scientific methodology. Dkt. 3858-2 at 1; *see, e.g.*, Dkt. 4090 at 92–93(Oct. 26 trial tr., vol. 16) (discounting Keyes' findings that the percentage of modern heroin users that started with prescription opioid use in the 2000s was 75%, by analyzing the Cicero paper, which concluded that heroin use as an initiating opioid grew sharply from 8.7% in 2005 to 31.6% in 2015); *Id.* at 106–07 (discounting Keyes conclusion about how addiction to heroin starts with

the use of a prescription opioid, by discussing the Muhuri study, which demonstrated that 97.7% of people who started heroin have used other illicit drugs besides prescription opioid pills before starting heroin).

- Dr. Lembke offered opinions far beyond her expertise and qualifications. Despite disclaiming any knowledge or expertise regarding the practice of pharmacy (and admittedly never having practiced, studied, or worked in a pharmacy), she offered expert opinions regarding pharmacies' national policies and dispensing practices. Dkt. 3915-2 at 1; *see, e.g.*, Dkt. 4000 at 182–83, 86–87 (Oct. 6, trial tr., vol. 3) (Dr. Lembke testifying that: (1) Defendants' policies and procedures were not effective or adequate to detect red flags; and (2) Defendants increased the supply of opioids and failed to provide effective controls against diversion, which led to opioid misuse and addiction).
- McCann offered no opinions about the validity of any of the criteria Plaintiffs' lawyers told him to use or the appropriateness of any of the dispensing transactions he flagged, relying entirely on counsel and other experts to make those determinations. His opinions were thus inherently arbitrary and unreliable. Dkt. 3866-2 at 1–2; *see* Dkt. 4032 at 61, 68–69 (Oct. 15, trial tr., vol. 9) (McCann testifying that he programmed algorithms that reflected flagging rules suggested by Plaintiffs' counsel and Catizone, and that the algorithms did not differentiate, among other things, between primary care physicians and specialists, between patients with chronic pain and patients who underwent various treatments, and between short-acting opioids and long-acting opioids).

CONCLUSION

For these reasons, the Court should grant judgment as a matter of law under Rule 50(a) in favor of Defendants.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system on all counsel of record on October 29, 2021.

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